

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Alain FOUERE et al. Confirmation No.: 4885
Appln. No. : 10/787,170 Group Art Unit : 3746
Filed : February 27, 2004 Examiner : P. Bianco
For : LACRYMAL PLUGS AND METHODS FOR SETTING SAME

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop **Appeal Brief - Patents**
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This appeal is from the Examiner's final rejection of claims 1 – 23 as set forth in the Final Office Action of May 19, 2006.

A Notice of Appeal and a Request for Pre-Appeal Brief Review in response to the May 19, 2006 Final Office Action were filed November 20, 2006 with a three-month extension of time. Further, a Notice of Panel Decision from Pre-Appeal Brief Review instructing Appellant to proceed to Board of Patent Appeals and Interferences was forwarded February 6, 2007. Accordingly, the instant Appeal Brief is being timely submitted by the initial due date of March 6, 2007.

The requisite fee under 37 C.F.R. 1.17(c) in the amount of \$ 250.00 for the filing of the Appeal Brief is being submitted herewith. However, if for any reason the necessary fee is not associated with this file, the undersigned authorizes the charging of any filing fees for the Appeal Brief and/or any necessary extension of time fees to Deposit Account No. 19 - 0089.

(1) REAL PARTY IN INTEREST

As the inventors have not executed an Assignment in favor of another party, the real party in interest is the inventors Alain FOUERE and Pierre BIGE.

(2) **RELATED APPEALS AND INTERFERENCES**

No related appeals and/or interferences are pending.

(3) **STATUS OF THE CLAIMS**

Claims 1 – 23 stand finally rejected.

(4) STATUS OF THE AMENDMENTS

No amendments have been entered subsequent to the Final Office Action of May 19, 2006.

However, in reviewing the Official File on the U.S. Patent and Trademark Office PAIR system and the published U.S. Application, Appellants note the amended specification appears incorrect. In this regard, while it appears the paragraph numbers identified in Appellants' preliminary amendment were incorrect, these amendments were properly entered by the U.S. Patent and Trademark Office personnel. However, it also appears the non-amended paragraphs were inadvertently deleted from the specification.

Accordingly, to ensure that the record is correct, Appellants are concurrently submitting a request to enter a Substitute Specification that includes the changes made during the prosecution of the instant application. Further, as this Substitute Specification merely enters previously submitted amendment, with revised paragraph numbering, no marked-up copy of the Substitute Specification is required.

Moreover, as entry of the Substitute Specification does not affect the claims on appeal, entry and consideration of this Substitute Specification is proper.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

The instant invention is directed to lachrymal plugs and a method for positioning such plugs. (Page 1, lines 7 - 10).

The following descriptions are made with respect to the independent claim and include references to particular parts of the specification. As such, the following is merely exemplary and is not a surrender of other aspects of the present invention that are also enabled by the present specification and that are directed to equivalent structures or methods within the scope of the claims.

Independent claim 1 is directed to a lachrymal plug that allows a blockage of the lachrymal ducts to overcome a deficiency of the lachrymal glands by decreasing or suppressing the flow of tears toward the nasal cavities, (Specification, page 2, line 29 – page 3, line 3) the lachrymal plug comprising: a substantially cylindrical body 10 having an external lateral wall (Specification, page 4, line 2) and flexible elements 11 attached to the external wall structured (Specification, page 4, line 2) and arranged to prevent migration so as to maintain said lachrymal plug in position (Specification, page 4, lines 5 – 8).

Independent claim 19 is directed to a method of positioning a lachrymal plug, the method comprising positioning in a lachrymal duct 4, 5 (Specification, page 4, lines 6) a substantially cylindrical body 10 (Specification, page 4, line 2) having external lateral wall and flexible elements 11 attached to the external wall structured (Specification, page 4, line 2) and arranged to prevent migration so as to maintain the lachrymal plug (Specification, page 4, lines 5 – 8).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(A) Claims 1 – 9, 11, and 18 – 20 are Rejected Under 35 U.S.C. § 102(e) as being Anticipated by WEBB et al. (U.S. Patent No. 6,629,533) [hereinafter “WEBB”];

(B) Claims 10, 15, and 21 are Rejected Under 35 U.S.C. § 103(a) as being Unpatentable over WEBB in view of MacKEEN et al. (U.S. Patent No. 4,915,684) [hereinafter “MacKEEN”];

(C) Claims 12 and 13 are Rejected Under 35 U.S.C. §103(a) as being Unpatentable over WEBB in view of FREEMAN (U.S. Patent No. 3,949,750);

(D) Claim 14 is Rejected Under 35 U.S.C. §103(a) as being Unpatentable over WEBB in view of HERRICK (U.S. Patent No. 5,163,959); and

(E) Claims 16, 17, 22, and 23 are Rejected Under 35 U.S.C. §103(a) as being Unpatentable over WEBB in view of SEDER et al. (U.S. Patent No. 4,959,048) [hereinafter “SEDER”].

(7) **ARGUMENT**

(A) The Rejection of Claims 1 – 9, 11, and 18 – 20 Under 35 U.S.C. § 102(e) as Anticipated by WEBB is in Error, the Rejection Should be Reversed, and the Application Should be Remanded to the Examiner.

The Examiner asserts WEBB shows all of the claimed features, and that the anchoring arms would be equivalent to the recited pins. Applicants traverse the Examiner's assertions.

In order to establish a *prima facie* case of anticipation under 35 U.S.C. § 102, a single prior art reference must disclose each and every element as set forth in the subject claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). Applicants respectfully submit that a *prima facie* case of anticipation cannot be established because CHUPKA fails to teach each and every element of the claims.

Independent Claim 1:

Applicants independent claim 1 recites, *inter alia*, a substantially cylindrical body having an external lateral wall, and flexible elements attached to the external wall *structured and arranged to straighten out when positioned* to maintain said lachrymal plug in position. Applicants submit that WEBB fails to show at least the above-noted features.

WEBB shows a punctum plug having a circumferentially radiating flexible anchoring arm to secure the plug in the punctum of the wearer. Moreover, WEBB's punctum plug has a large head to provide external support when the plug is secured in the punctum, whereas the present invention is a lachrymal plug positionable within the

canalicular duct.

A review of WEBB reveals that, while disclosing an anchoring arm that can fold to accommodate narrow punctal openings, WEBB fails to disclose this anchor arm is *structured and arranged to straighten out when positioned to maintain the plug in position*, as recited in at least independent claim 1. Applicants submit the Examiner's interpretation of WEBB is based upon Applicants' disclosure and not upon any specific teaching of WEBB. Further, Applicants note the Examiner has not identified any specific teaching in WEBB that even arguably discloses the anchor arm of WEBB is structured and arranged to straighten out when positioned to maintain the plug in position, as recited in at least independent claim 1.

In particular, Applicants submit WEBB fails to provide any disclosure regarding positioning of the flexible anchoring arms after the punctum plug is inserted. While WEBB discloses that a portion of the anchoring arm should extend a distance greater than the width of the head, there is no teaching or suggestion, absent Applicants' own disclosure, that the anchoring arm of WEBB straightens out when positioned, as recited in the pending claims.

Because WEBB fails to show at least the above-noted features, Applicants submit that the applied art fails to disclose each and every recited feature of the claims. Therefore, Applicants submit that the applied art fails to provide an adequate evidentiary basis to support a rejection of anticipation under 35 U.S.C. § 102(e), and that the present rejection is improper and should be withdrawn.

Independent Claim 19:

Applicants' independent claim 19 recites, *inter alia*, positioning in a lachrymal

duct a substantially cylindrical body having external lateral wall and flexible elements attached to the external wall *structured and arranged to straighten out when positioned* to maintain the lachrymal plug. Appellants submit WEBB fails to disclose at least the above-noted features of the invention.

WEBB shows a punctum plug having a circumferentially radiating flexible anchoring arm to secure the plug in the punctum of the wearer. Moreover, WEBB's punctum plug has a large head to provide external support when the plug is secured in the punctum, whereas the present invention is a lachrymal plug positionable within the canalicular duct.

A review of WEBB reveals that, while disclosing an anchoring arm that can fold to accommodate narrow punctal openings, WEBB fails to disclose this anchor arm is *structured and arranged to straighten out when positioned to maintain the plug in position*, as recited in at least independent claim 19. Applicants submit the Examiner's interpretation of WEBB is based upon Applicants' disclosure and not upon any specific teaching of WEBB. Further, Applicants note the Examiner has not identified any specific teaching in WEBB that even arguably discloses the anchor arm of WEBB is structured and arranged to straighten out when positioned to maintain the plug in position, as recited in at least independent claim 19.

In particular, Applicants submit WEBB fails to provide any disclosure regarding positioning of the flexible anchoring arms after the punctum plug is inserted. While WEBB discloses that a portion of the anchoring arm should extend a distance greater than the width of the head, there is no teaching or suggestion, absent Applicants' own disclosure, that the anchoring arm of WEBB straightens out when positioned, as recited

in the pending claims.

Because WEBB fails to show at least the above-noted features, Applicants submit that the applied art fails to disclose each and every recited feature of the claims. Therefore, Applicants submit that the applied art fails to provide an adequate evidentiary basis to support a rejection of anticipation under 35 U.S.C. § 102(e), and that the present rejection is improper and should be withdrawn.

Dependent Claims:

Further, Applicants note that, as WEBB merely discloses the use of a circumferentially radiating securing arm, the Examiner's assertions that the arm is equivalent to radial pins is based upon no specific teaching in WEBB, but is based solely upon Applicants' own disclosure. In this regard, Applicants note the Examiner has not pointed to any specific teaching in WEBB in support of his assertions, nor can he.

Therefore, Applicants submit, when considered solely upon its own disclosure, WEBB cannot even arguably anticipate the radial pins recited in claims 2 and 20, the arrangement of the pins recited in claims 3 – 7, an additional disk to ensure impermeability recited in claim 8, the manner in which the pins straighten out recited in claim 9, the specifics of the body recited in claim 11, or the manner in which the flexible elements straighten out recited in claim 18.

Still further, as the Examiner's rejections of the dependent claims rely on equivalence, Applicants submit this is not a proper basis for an anticipation rejection under 35 U.S.C. § 102(e). Accordingly, for this additional reason, Applicants submit the instant rejection is improper and must be reversed and remanded to the examining

group for allowance.

Further, in addition to foregoing distinguishing features of the dependent claims, Applicants submit that claims 2 – 9, 11, 18, and 20 are allowable at least for the reason that each of these claims depend from an allowable base claim and because each of these claims further define the features of the invention.

Therefore, Appellants respectfully request that the Board reverse the Examiner's decision to finally reject 1 – 9, 11, and 18 – 20 under 35 U.S.C. § 102(e), and that the application be remanded to the Examiner for withdrawal of the rejection over CHUPKA and an early allowance of all claims on appeal.

(B) The Rejection of Claims 10, 15, and 21 Under 35 U.S.C. § 103(a) as being Unpatentable over WEBB in view of MacKEEN is in Error, the Rejection Should be Reversed, and the Application Should be Remanded to the Examiner.

While acknowledging that WEBB fails to show a punctum plug having an axial duct for the passage of tears and a specific insertion tool, the Examiner asserts that MacKEEN shows these features, and asserts it would have been obvious to modify WEBB to include the same.

Applicants note that MacKEEN shows a device for modulating flow of lachrymal fluid, which includes an arcuate head, a cylinder, and a peripheral member. However, notwithstanding the features the Examiner asserts are disclosed by MacKEEN, Applicants note MacKEEN, like WEBB, fails to teach or suggest the recited flexible elements that are structured and arranged to straighten out to maintain the position of the plug, as recited in the independent claims.

Thus, as neither applied document teaches or suggests at least the above-noted features of at least independent claims 1 and 19, Applicants submit that no proper combination of WEBB in view of MacKEEN can even arguably render unpatentable the instant invention. Thus, Applicants submit the pending rejection is improper and should be withdrawn.

Further, Applicants submit it would not have been obvious to modify WEBB to utilize a tool such as disclosed by MacKEEN.

A rejection under 35 U.S.C. § 103(a) requires the Examiner to first establish a prima facie case of obviousness: "The Examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the Examiner does not produce a prima facie case, the Appellants are under no obligation to submit evidence of nonobviousness." MPEP 2142. The Court of Appeals for the Federal Circuit has set forth three elements, which must be shown for prima facie obviousness:

"First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teachings or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)."

Appellants note, as the punctum plug of WEBB is simply inserted into the wearer's punctum, such that a head portion of the punctum plug remains outside of the punctum, no special tools are necessary for insertion. As no special tools are necessary to facilitate insertion of the punctum plug of WEBB into the patient's punctum, Appellants submit the art of record fails to provide the requisite rationale or

motivation to utilize a specific tool, such as taught by MacKEEN.

Further, in establishing a *prima facie* case of obviousness under 35 U.S.C. § 103, it is incumbent upon the Examiner to provide a reason *why* one of ordinary skill in the art would have found it obvious to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. See *Ex parte Clapp*, 227 USPQ 972 (B.P.A.I. 1985). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from Appellant's disclosure. See, for example, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988). It is respectfully submitted that the courts have long held that it is impermissible to use Appellant's claimed invention as an instruction manual or "template" to piece together teachings of the prior art so that the claimed invention is purportedly rendered obvious. See *In re Fritch*, 972 R.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992).

Appellants submit the Examiner has shown no teaching or suggestion in the applied art of record to support his assertions that it would have been obvious to modify WEBB in view of MacKEEN, nor has the Examiner identified any teaching as to why one ordinarily skilled in the art would have modified WEBB in the manner asserted by the Examiner. In particular, Appellants submit there is no arguable suggestion provided in the applied art of record as to why one ordinarily skilled in the art would modify WEBB so as to utilize the MacKEEN tool for insertion into a patient's punctum.

Still further, the applied art fails to provide any teaching or suggestion as to how one ordinarily skilled in the art would utilize an insertion device such as MacKEEN with

a punctum plug such as disclosed by WEBB. In this regard, Appellants submit it is not apparent from the disclosures of the cited documents how one ordinarily skilled in the art would have utilized the MacKEEN insertion tool with the WEBB punctum plug.

Because the art of record fails to provide any teaching or suggestion for combining the art of record in the manner asserted by the Examiner, Applicants submit that the instant rejection is based upon an improper combination of documents, which renders the rejection improper.

Further, in addition to foregoing distinguishing features of the dependent claims, Applicants submit that claims 10, 15, and 21 are allowable at least for the reason that each of these claims depend from an allowable base claim and because each of these claims further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claims 10, 15, and 21 under 35 U.S.C. § 103(a) and indicate that these claims are allowable.

Accordingly, Appellant respectfully requests that the decision of the Examiner to finally reject claims 1 - 37 under 35 U.S.C. § 102(b) be reversed, and that the application be remanded to the Examiner for withdrawal of the rejection over SHEARER and an early allowance of all claims on appeal.

(C) The Rejection of Claims 12 and 13 Under 35 U.S.C. §103(a) as being Unpatentable over WEBB in view of FREEMAN is in Error, the Rejection Should be Reversed, and the Application Should be Remanded to the Examiner.

The Examiner asserts, while WEBB fails to show the insert is made of metal or

shape memory steel, it would have been obvious to modify WEBB to include an insert being made of metal or shape memory steel, as taught by FREEMAN. Applicants traverse the Examiner's assertions.

Applicants note WEBB fails to teach or suggest flexible elements *structured and arranged to straighten out when positioned*. Moreover, this document fails to provide any teaching or suggestion of forming the flexible securing arm from metal.

While FREEMAN discloses a punctum plug formed of metal, FREEMAN fails to provide any teaching or suggestion that the plug and/or any elements of the plug are flexible. Moreover, Applicants submit that FREEMAN fails to provide any teaching or suggestion of flexible elements *structured and arranged to straighten out when positioned* to maintain the position of the plug, as recited in at least independent claim 1.

As neither WEBB nor FREEMAN teaches or suggests at least the above-noted feature of at least independent claim 1, Applicants submit that no proper combination of these documents can render unpatentable the instant invention.

Further, Applicants submit, as there is no teaching or suggestion in the art of record of forming flexible elements from metal, it would not have been obvious to modify WEBB to be formed from metal, as disclosed by FREEMAN.

Because the art of record fails to provide any teaching or suggestion for combining the art of record in the manner asserted by the Examiner, Applicants submit that the instant rejection is based upon an improper combination of documents, which renders the rejection improper.

Further, Applicants submit that claims 12 and 13 are allowable at least for the

reason that each of these claims depend from an allowable base claim and because each of these claims further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claims 12 and 13 under 35 U.S.C. § 103(a) and indicate that these claims are allowable.

(D) The Rejection of Claim 14 Under 35 U.S.C. §103(a) as being Unpatentable over WEBB in view of HERRICK is in Error, the Rejection Should be Reversed, and the Application Should be Remanded to the Examiner.

The Examiner asserts that, while WEBB fails to show the insert being made of a radio-opaque material that is visible with X-rays, but that it would have been obvious to modify WEBB to include an insert being made of radio-opaque material, as taught by HERRICK. Applicants traverse the Examiner's assertions.

As noted above, WEBB fails to teach or suggest flexible elements structured and arranged to straighten out when positioned to maintain a position of the plug, as recited in at least independent claim 1.

Further, while HERRICK discloses a canalicular implant, there is no teaching or suggestion of flexible elements, and certainly no suggestion of flexible elements structured and arranged to straighten out when positioned to maintain a position of the plug, as recited in at least independent claim 1.

Because neither document teaches or suggests at least the above-noted feature of at least independent claim 1, Applicants submit that no proper combination of these documents can render unpatentable the instant invention.

Moreover, Applicants submit, as WEBB is directed to an externally supported punctum plug and HERRICK is directed to a canalicular implant, these elements are structurally designed for specific uses in different places. Because these elements are distinctly designed for distinct purposes and uses, Applicants submit that the art of record fails to provide any teaching or suggestion for combining these teachings in any manner that would render unpatentable the present invention. Accordingly, Applicants submit that the instant rejection is based upon an improper combination of documents, which renders the rejection improper.

Further, Applicants submit that claim 14 is allowable at least for the reason that it depends from an allowable base claim and because it further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the rejection of claim 14 under 35 U.S.C. § 103(a) and indicate that these claims are allowable.

(E) The Rejection of Claims 16, 17, 22, and 23 Under 35 U.S.C. §103(a) as being Unpatentable over WEBB in view of SEDER is in Error, the Rejection Should be Reversed, and the Application Should be Remanded to the Examiner.

The Examiner asserts WEBB shows the recited subject matter with the exception of the tool used to implant the plug having jaws, but that it would have been obvious to modify WEBB to include a tool having jaws, as taught by SEDER. Applicants traverse the Examiner's assertions.

As noted above, WEBB fails to disclose flexible elements structured and

arranged to straighten out when positioned to maintain a position of the plug.

Further, while SEDER discloses a lacrimal duct occluder, Applicants submit there is no teaching or suggestion of flexible elements, and certainly no suggestion of flexible elements structuring and arranging flexible elements to straighten out when positioned to maintain a position of the plug, as recited in at least independent claims 1 and 19.

Further, Applicants submit it would not have been obvious to modify WEBB to utilize a tool such as disclosed by SEDER. In particular, it is noted that, as the punctum plug of WEBB is simply inserted into the wearer's punctum, no special tools are necessary for insertion/removal, such that there appears to be no rationale or motivation to utilize a specific tool, such as taught by SEDER, since to do so would only appear to complicate WEBB's insertion/removal procedure.

Because the art of record fails to provide any teaching or suggestion for combining the art of record in the manner asserted by the Examiner, Applicants submit that the instant rejection is based upon an improper combination of documents, which renders the rejection improper.

Because neither document teaches or suggests at least the above-noted feature of at least independent claims 1 and 19, Applicants submit that no proper combination of these documents can render unpatentable the instant invention.

Further, Applicants submit that claims 16, 17, 22, and 23 are allowable at least for the reason that each of these claims depend from an allowable base claim and because each of these claims further define the features of the invention.

Accordingly, Applicants request that the examiner reconsider and withdraw the

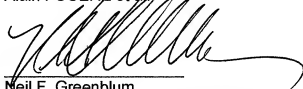
rejection of claims 16, 17, 22, and 23 under 35 U.S.C. § 103(a) and indicate that these claims are allowable.

(C) Conclusion

Claims 1 – 9, 11, and 18 – 20 are patentable under 35 U.S.C. § 102(e) over WEBB; Claims 10, 15, and 21 are patentable over WEBB in view of MacKEEN; Claims 12 and 13 are patentable over WEBB in view of FREEMAN; Claim 14 is patentable over WEBB in view of HERRICK; and Claims 16, 17, 22, and 23 are patentable over WEBB in view of SEDER. Specifically, the applied art of record fails to anticipate or render unpatentable the unique combination of features recited in Appellants' claims 1 – 23. Accordingly, Appellants respectfully request that the Board reverse the Examiner's decision to finally reject claims 1 – 23 under 35 U.S.C. § 102(b) or 35 U.S.C. § 103(a) and remand the application to the Examiner for withdrawal of the rejection.

Thus, Appellants respectfully submit that each and every pending claim of the present application meets the requirements for patentability under 35 U.S.C. §112, second paragraph, 35 U.S.C. §102(b), and 35 U.S.C. §103(a), and that the present application and each pending claim are allowable over the prior art of record.

Respectfully submitted,
Alain FOUERE et al.



Neil F. Greenblum
Reg. No. 28,394

Robert W. Mueller
Reg. No. 35,043

March 5, 2007
GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place

Reston, VA 20191
(703) 716-1191

Attachments: Claims Appendix
Evidence Appendix
Related Proceedings Appendix

8) CLAIMS APPENDIX

The following listing of claims is a listing of all pending claims in the instant application:

Listing of Claims

1. (Previously presented) A lachrymal plug that allows a blockage of the lachrymal ducts to overcome a deficiency of the lachrymal glands by decreasing or suppressing the flow of tears toward the nasal cavities, the lachrymal plug comprising:
a substantially cylindrical body having an external lateral wall; and
flexible elements attached to the external wall structured and arranged to prevent migration so as to maintain said lachrymal plug in position.
2. (Previously presented) The lachrymal plug according to claim 1, wherein the flexible elements comprise radial pins.
3. (Previously presented) The lachrymal plug according to claim 2, wherein the pins are tilted in a direction of the nasal cavities, and
wherein the lachrymal plug cannot be displaced by a natural peristalsis of the lachrymal duct driving tears and foreign bodies inwardly.
4. (Previously presented) The lachrymal plug according to claim 2 wherein the pins have a constant length.
5. (Previously presented) The lachrymal plug according to claim 2 wherein the

pins have a variable length.

6. (Previously presented) The lachrymal plug according to claim 5, wherein the pins have an increasing or decreasing length.

7. (Previously presented) The lachrymal plug according to claim 2 wherein the pins are arranged in helical formation around the body .

8. (Previously presented) The lachrymal plug according to claim 1 further comprising:

at least one flexible disk arranged to ensure impermeability.

9. (Previously presented) The lachrymal plug according to claim 2 wherein the flexible elements have sufficient elasticity to partially penetrate into an inner wall of the lachrymal canaliculus by straightening, to ensure that the lachrymal plug is firmly held in position.

10. (Previously presented) The lachrymal plug according to claim 1 further comprising:

an axial duct having a reduced passage for tears.

11. (Previously presented) The lachrymal plug according to claim 1 wherein the body has a cone, a double cone, or a diabolo shape.

12. (Previously presented) The lachrymal plug according to claim 1 wherein the lachrymal plug is made of metal.

13. (Previously presented) The lachrymal plug according to claim 1 wherein the lachrymal plug is made of shape memory metal.

14. (Previously presented) The lachrymal plug according to claim 1 wherein the lachrymal plug comprises a radio-opaque reference that is visible with X-rays, to facilitate marking during its progression when it is positioned.

15. (Previously presented) A method of positioning the lachrymal plug according to claim 1 comprising:

positioning the lachrymal plug with a tube having a push rod, structured and arranged to allow pressing of pins against an outer wall of the cylindrical body and to release the pins once the lachrymal plug is in position.

16. (Previously presented) A method of positioning the lachrymal plug according to claim 1 comprising:

positioning the lachrymal plug with an instrument provided with jaws.

17. (Previously presented) The method of positioning the lachrymal plug according to claim 16 further comprising:

removing the lachrymal plug with the instrument provided with jaws.

18. (Previously presented) The lachrymal plug according to claim 1 wherein the flexible elements are structured and arranged to collapse against the external walls to allow insertion of the lachrymal plug in the lachrymal duct and straighten when released in the lachrymal duct.

19. (Previously presented) A method of positioning a lachrymal plug, the method comprising:

positioning in a lachrymal duct a substantially cylindrical body having external lateral wall and flexible elements attached to the external wall structured and arranged to prevent migration so as to maintain the lachrymal plug.

20. (Previously presented) The method according to claim 19, wherein the flexible elements comprise radial pins.

21. (Previously presented) The method of positioning the lachrymal plug according to claim 19 further comprising:

positioning the lachrymal plug with a tube having a push rod that is structured and arranged to allow pressing the pins against an outer wall of the cylindrical body and to release the pins once the lachrymal plug is in position.

22. (Previously presented) The method according claim 19 further comprising:

positioning the lachrymal plug with an instrument provided with jaws.

23. (Previously presented) The method according to claim 22 further comprising:
removing the lachrymal plug with the instrument provided with jaws.

(9) **EVIDENCE APPENDIX**

None.

(10) RELATED PROCEEDINGS APPENDIX

None.